



1FW 1654

PTO/SB/21 (09-06)

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| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 10/575,938 | |
| | Filing Date | 4/13/06 | |
| | First Named Inventor | Thoene | |
| | Art Unit | 1654 | |
| | Examiner Name | Unassigned | |
| Total Number of Pages in This Submission | 6 | Attorney Docket Number | TUL5AUSA |

| ENCLOSURES (Check all that apply) | | |
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| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below): |
| Remarks Customer No. 00270 | | |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | | | |
|--|---------------------|----------|--------|
| Firm Name | Howson & Howson LLP | | |
| Signature | <i>Mary E. Bak</i> | | |
| Printed name | Mary E. Bak | | |
| Date | Feb 27, 2007 | Reg. No. | 31,215 |

| CERTIFICATE OF TRANSMISSION/MAILING | | | |
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| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: | | | |
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| Typed or printed name | Summer Uchin | Date | 2/27/2007 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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TUL5AUSA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/575,938 Confirmation No.: 7083
Applicant : Thoene
Filed : April 13, 2006
TC/A.U. : 1654
Examiner :
Customer No. : 00270
Title : METHODS AND COMPOSITIONS FOR TREATING
CANCER

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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INFORMATION DISCLOSURE STATEMENT

Sir:

Applicant submits to the Examiner the attached document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98. The forms are attached and copies of the documents are enclosed herewith. This Information Disclosure Statement is submitted more than three months from the filing date of this application, before the receipt of a first Office Action. Therefore, no fees are believed due.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or during the pendency of this application, or credit any overpayment in any fees to our Deposit Account No. 08-3040.

REMARKS

Listed below are documents cited in the International Search Report dated July 24, 2006 in the corresponding International Patent Application No. PCT/US04/32305. A copy of the Report is enclosed, together with copies of these documents.

- (i) PISONI et al., "Description of a Selection Method Highly Cytotoxic for Cystinotic Fibroblasts but not Normal Human Fibroblasts", Somatic Cell Molecular Genetics, 18(1):1-6 (January 1992)
- (ii) OIRY et al., "Synthesis and Radioprotective Activity of Dipeptide Cysteamine and Cystamine Derivatives", J. Med. Chem. 32:297-301 (1989)

The month of publication for documents AAU, BX, and BZ could not be determined. The years of publication for these documents are sufficiently earlier than the effective US filing date and/or the foreign priority date of the present application so that the particular month of publication of the documents is not in issue (MPEP 609).

Applicants also noted that document AAX was made available to attendees at the American Society of Human Genetics, 53rd Annual Meeting on November 4-8, 2003 in Los Angeles, CA. Applicants were also advised that this abstract was contained in a program/abstract volume, which was mailed to registrants on September 19, 2003.

The Examiner is respectfully requested to consider the enclosed documents identified in this paper and in the attached forms during the course of examination of this application.

Respectfully submitted,

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Attorneys for Applicants

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

| | |
|------------------------|------------|
| Application Number | 10/575,938 |
| Filing Date | 4/13/2006 |
| First Named Inventor | Thoene |
| Art Unit | 1654 |
| Examiner Name | Unassigned |
| Attorney Docket Number | TUL5AUSA |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T ² |
|--------------------|-----------------------|---|----------------|
| | AR | AFFORD et al., "Demystified...Apoptosis", J. Clin. Pathol.: Mol. Pathol., 53:55-63 (April 2000) | |
| | AS | BUSCHINI et al., "Saccharomyces cerevisiae as an Eukaryotic Cell Model to Assess Cytotoxicity and Genotoxicity of Three Anticancer Anthraquinones", Mutagenesis, 18(1):25-36 (January 2003) | |
| | AT | COLEMAN et al., "Membrane Blebbing During Apoptosis Results from Caspase-Mediated Activation of ROCK I", Nature Cell Biol., 3:339 (April 2001) | |
| | AU | CHU et al., "PKC Isozyme S-cysteinylolation by Cystine Stimulates the Pro-Apoptotic Isozyme PKCδ and Inactivates the Ocogenic Isozyme PKCε", Carcinogenesis, 24(2):317-325 (February 2003) | |
| | AV | CHU et al., "Cellular Protein Kinase C Isozyme Regulation by Exogenously Delivered Physiological Disulfides - Implications of Oxidative Protein Kinase C Regulation to Cancer Prevention", Carcinogenesis, 25(4):585-596 (April 2004; E Pub: December 4, 2003) | |
| | AW | HELIP-WOOLEY et al., "Expression of CTNS Alleles: Subcellular Localization and Aminoglycoside Correction in Vitro", Mol. Genetics and Metabol., 75:128-133 (February 2002) | |
| | AX | KANDUC et al., "Cell Death: Apoptosis Versus Necrosis (Review)", Int. J. Oncol., 21:165-170 (July 2002) | |
| | AY | KANG et al., "A Role for Uric Acid in the Progression of Renal Disease", J. Am. Soc. Nephrol., 13:2888-2897 (December 2002) | |
| | AZ | KAUFMANN et al., "Induction of Apoptosis by Cancer Chemotherapy", Exp. Cell. Res., 256:42-49 (April 10, 2000) | |
| | AAR | LEMONS et al., "Elevated Temperature Produces Cystine Depletion of Cystinotic Fibroblasts", Biochim. et Biophys. Acta 884:429-434 (December 10, 1986) | |
| | AAS | OIRY et al., "Synthesis and Radioprotective Activity of Dipeptide Cysteamine and Cystamine Derivatives", J. Med. Chem. 32:297-301 (February 1989) | |
| | AAT | OSHIMA et al., "Cystine Metabolism in Human Fibroblasts", J. Biol. Chem., 251(14):4287-4293 (July 25, 1976) | |
| | AAU | PARK et al., "Cystinotic Fibroblasts Display Aberrant Apoptosis", Am. J. Hum. Genetics, 69(4), Abstract 1774 (2001) | |
| | AAV | PARK et al., "Potential Role of Apoptosis in Development of the Cystinotic Phenotype", Pediatr. Nephrol., 20:441-446 (April 2005 - E Pub: December 28, 2004) | |
| | AAW | PARK et al., "Lysosomal Cystine Storage Augments Apoptosis in Cultured Human Fibroblasts and Renal Tubular Epithelial Cells", J. Am. Soc. Nephrol., 13:2878-2887 (December 2002) | |

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| Examiner Signature | Date Considered |
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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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| | | | | Application Number | 10/575,938 |
| | | | | Filing Date | 4/13/2006 |
| | | | | First Named Inventor | Thoene |
| | | | | Art Unit | 1654 |
| | | | | Examiner Name | Unassigned |
| Sheet | 2 | of | 3 | Attorney Docket Number | TUL5AUSA |

| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|-----------------------|---|----------------|--|
| Examiner Initials* | Cite No. ¹ | Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T ² | |
| | AAX | PARK et al., "Mouse L929 Fibroblasts do not Display Increased Apoptosis Following Lysosomal Cystine Loading with CDME", American Society of Human Genetics, 53 rd Annual Meeting, Los Angeles, CA, Biochemical Genetics Poster #42 (2003) | | |
| | AAY | PISONI et al., "Detection and Characterization of a Transport System Mediating Cysteamine Entry into Human Fibroblast Lysosomes", J. Biol. Chem., 270(3):1179-1184 (January 20, 1995) | | |
| | AAZ | PISONI et al., "Important Differences in Cationic Amino Acid Transport by Lysosomal System c and System y ⁺ of the Human Fibroblast", J. Biol. Chem., 262(31):15011-15018 (November 5, 1987) | | |
| | BR | PISONI et al., "Detection and Characterization of Carrier-Mediated Cationic Amino Acid Transport in Lysosomes of Normal and Cystinotic Human Fibroblasts", J. Biol. Chem., 260(8):4791-4798 (April 25, 1985) | | |
| | BS | PISONI et al., "Description of a Selection Method Highly Cytotoxic for Cystinotic Fibroblasts but not Normal Human Fibroblasts", Somatic Cell Molecular Genetics, 18(1):1-6 (January 1992) | | |
| | BT | PISONI et al., "Utilization of Mercaptoethylgluconamide for Depleting Human Cystinotic Fibroblasts of their Accumulated Lysosomal Cystine", 26(1): 73-76 (July 1989) | | |
| | BU | SAUTER et al., "Consequences of Cell Death: Exposure to Necrotic Tumor Cells, but Not Primary Tissue Cells or Apoptotic Cells, Induces the Maturation of Immunostimulatory Dendritic Cells", J. Exp. Med., 191(3): 423 (February 7, 2000) | | |
| | BV | SCHNEIDER et al., "Ineffectiveness of Ascorbic Acid Therapy in Nephropathic Cystinosis", N. Engl. J. Med., 300:756 (April 5, 1979) | | |
| | BW | SHIOKAWA et al., "Involvement of DNase γ in Apoptosis Associated with Myogenic Differentiation of C2C12 Cells", J. Biol. Chem., 277(34):31031-31037 (August 23, 2002) | | |
| | BX | THOENE et al., "Advances in Understanding the Pathophysiology of Cystinosis and Lysosomal Biogenesis", Cystinosis Research Network Newsletter, Fall 2003 | | |
| | BY | THOENE et al., "Mutations of CTNS Causing Intermediate Cystinosis", Mol. Genetics Metabol., 67:283-293 (August 1999) | | |
| | BZ | THOENE et al., "Cystine Depletion of Cystinotic Cells by Amino thiols", Proc. Roy. Soc. Med., 70(3):37-40 (1977) | | |
| | BBR | THOENE et al., "Inhibitors of Protein Synthesis Also Inhibit Lysosomal Proteolysis Studies Using Cystinotic Fibroblasts", J. Clin. Invest., 75:370-376 (February 1985) | | |

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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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